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Outcomes of the conventional and biological treatment approaches for the management of caries in the primary dentition

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Summary

Background. In the last few years conventional restorations including complete removal of carious tissue (CT) with or without pulp therapy for the treatment of carious lesions (CL) in primary teeth have been challenged and a more biological approach has been suggested. This approach involves the use of less invasive techniques which alter the environment of the CL isolating it from the cariogenic biofilm and substrate. Two of these treatment approaches that are becoming increasingly widely accepted and used in paediatric dentistry, are the Hall Technique and indirect pulp capping (IPC).

Aim. To investigate the outcome of the conventional versus the biological approaches for the treatment of deep CL in the primary teeth in children, delivered in a specialist paediatric dentistry training environment.

Design. This was a retrospective cohort study of 246 children aged 4-9 years, treated with either approach, conventional and biological, in two UK specialist hospital settings. Data was extracted from clinical dental records and post-operative radiographs of patients treated during the period 2006–2012. The outcome of the treatment in the current study was categorised into three main categories; clinical, radiographic and final outcome. Clinical and final outcomes were further described as success, minor and major failure.

Results. In total 836 primary teeth were included. In the conventional approach, 324 teeth had complete CT removal and 104 teeth had a pulpotomy. In the biological approach, 388 teeth had Hall Technique preformed metal crowns (PMC) placed and 20 teeth received indirect pulp capping. PMC were the restoration of choice for most of the cases where a pulpotomy had been carried out, and resin composite was most frequently used restorative material for the complete CT removal group.

The majority of the primary teeth treated with either approach remained asymptomatic after a follow-up period of up to 77 months; 95.3% in the conventional and 95.8% in the biological. No significant association was found between the final outcome and the approach used for treatment, age of the patient, gender, and number of carious surfaces or tooth type.

Conclusion. Both the conventional and biological treatment approaches had similar final outcomes and were equally successful for management of CL in the primary dentition.
Author contributions: A.B., M.D. and C.D. conceived the ideas; A.B. collected the data; A.B. analysed the data; A.B., M.D. and C.D. all contributed to the writing.

Introduction

Although many children in the United Kingdom (UK) enjoy good oral health in comparison to children worldwide, large numbers still suffer from dental disease and are in need of dental care. In 2013, 31% and 46% of 5 and 8 year olds, respectively in England, Wales and Northern Ireland had obvious caries experience in their primary teeth, of which 28% of 5 year olds and 39% of 8 year olds had untreated CL into dentine[1].

In the last few years the conventional restorations for the treatment of CL in primary teeth including complete removal of CT followed by suitable filling material with or without pulp therapy have been challenged and a more biological approach has been suggested[2,3].

This approach involves less invasive techniques which are aimed at altering the environment of the CL, no longer favouring progression by isolating the lesion from the cariogenic biofilm and substrate [2,3,4]. Two of these treatment approaches that are becoming increasingly widely accepted and used for restoring carious primary teeth, are the Hall Technique and the increasing use of incomplete CT removal, followed by indirect pulp capping (IPC) for deep CL. In the Hall Technique, CT is sealed into the tooth by means of preformed metal crown (PMC) and its luting cement[5], whereas in IPC, non-remineralisable CT is removed and a layer of affected but remineralisable CT is left at the deepest sites of the cavity preparation[6]. Over the last decade or so, the evidence base supporting the biological approach has been steadily increasing[2, 3, 5-15].

Inevitably, this has given rise to a growing trend towards a biological approach by paediatric dentists and has led to an increasing concern about the merits of the conventional approach and whether to retain this treatment modality as the standard technique in restoring primary teeth, or to adopt the biological approach as the treatment norm.

Few studies have directly compared the conventional and the biological approaches for the treatment of deep CL in primary teeth, with contradicting views reported on each treatment.

In an RCT conducted over a 5 year period, it was found that Hall Technique was more successful when compared to the conventional restoration[9,14]. However the majority of the restorations in the conventional arm were conventional glass ionomer cement in class II cavities which are known to have an increased failure rate when used for restoration of multiple surface lesions[16].

On the other hand, total CT removal has been reported to show higher overall clinical and radiographic success rate (96%) for the treatment of deep CL in primary molars during a 2 year follow-up period when compared to partial CT removal (92%)[17].

It has also been suggested that the biological approach would not be as successful as the conventional approach in the hands of specialists as had been reported in primary care based trials[9]. In light of this debate and conflicting reports in the literature, this two paediatric specialist centre retrospective cohort study aimed to compare the biological and conventional approaches for the treatment of deep CL in primary teeth in children.

Such a study would be essential before any recommendations could be made on the possible treatment modalities for carious primary teeth and would contribute to the current debate about these two treatment approaches.

Material and Methods

Study design and ethical approval

The study was conducted in two dental hospitals in the North of England, UK; Leeds (Leeds Dental Institute) and Sheffield (School of Clinical Dentistry, University of Sheffield). Differing treatment approaches are practiced in these two dental centres. In the Leeds Dental Institute (LDI), a conventional approach is predominantly practiced, whereas a biological

approach is the mainstay of dental treatment of the carious primary dentition in the School of Clinical Dentistry, University of Sheffield (SCD). The conventional approaches included for the purposes of this study were complete CT removal with or without pulp therapy of primary teeth, with pulp therapy including both pulpotomy and pulpectomy. The biological approaches included in the study were only either restorations placed using the principles of indirect pulp capping (IPC) or the Hall Technique.

Approval was obtained from the Dental Research Ethics Committee (DREC), University of Leeds. The study sample was identified from clinical dental records of paediatric patients who were treated at the two participating centres and who had received dental treatment by either approach, conventional, in LDI and biological in SCD, from 2006-2012.

Clinical records were identified using the computer system in these two centres and were reviewed alphabetically by the author (A.B.). Patient`s clinical records were included in the study if the patient met the following criteria:

- Aged 4 to 9 years at the time of dental treatment.
- Patient with no significant health problem (ASA Physical Status-1 and 2).
- Patient had at least one primary tooth (molar or anterior) with the CL extending into dentine on radiographs.
- Tooth had no history of infection or swelling and no evidence of periapical pathosis on initial clinical and radiographic diagnosis. In addition, teeth were asymptomatic or showed signs of reversible pulpitis.
- Pre-operative radiographs were available.
- Received conventional or biological restorations performed with or without the use of local anaesthesia (LA), inhalation sedation or general anaesthesia (GA) by specialists in

paediatric dentistry or paediatric post graduate students under supervision of specialist staff during the period of 2006-2012.

Patient clinical records were excluded if:

- CL confined to enamel radiographically.
- Teeth with clinical and radiographic evidence of irreversible pulpitis or periapical pathology on initial diagnosis.
- There was a break in the continuity of the record of more than one year.
- There was insufficient recorded information about the initial diagnosis of the teeth, treatment received and outcome of the treatment provided.
- There was any doubt about the source of the pain or the outcome of the treatment provided. Pain not resulting from caries such as mucosa lesions, or discomfort from exfoliating teeth was excluded.

Data on treatments performed and the outcome of treatment visits, recall visits, emergency appointments and post-operative radiographs were recorded on a standardised data abstraction proforma by a trained data abstractor (A.B.). The intra-examiner reliability was calculated using Kappa score and was found to equal 0.90.The data set also included age of the patient at time of treatment, gender, the notation and initial diagnosis of each CL (one or two surfaces cavity), and type of restoration placed.

The history of each treatment provided was followed through the clinical notes and post-operative radiographs to determine the final outcome. A pilot study was carried out before the start of the main study to assess the feasibility and ease of the data collection. Neither the study protocol nor the data extraction proforma were modified after the pilot study. Data extracted from patients` records for the pilot study were included in statistical analysis of the main study.

Sample size calculation

Data obtained from the pilot study were used to calculate the power and sample size of this retrospective cohort study using PASS (Power Analysis and Sample Size) software (version 11.0.8; PASS, NCSS, LLC). Moreover, power and sample size calculation was based on the final outcome "Successful"; teeth remained asymptomatic in place till the last follow-up visit. The total number of teeth obtained in the conventional and biological approaches in the pilot study were 92 and 50 teeth, respectively. In addition, 96% of the teeth in the conventional approach remained asymptomatic in place compared to 100% for the teeth in the biological approach. Based on this data, it was found that a minimum of 192 teeth were required in each treatment approach in order to achieve 80% power to detect a difference between the group proportions of 0.0400 using the two-sided Z test with pooled variance and significant level at $P<0.05$. As some patients included in the study had more than one restored primary tooth with either approach, the sample size was adjusted for clustering.

Outcomes of the treatment

The outcome of treatment in the current study was categorised into three main categories; clinical, radiographic and final outcome.

The clinical outcome was defined as the clinical fate of the tooth following the dental intervention as seen over the follow-up visits. However, the radiographic outcome assessed the treatment as seen on radiographs such as pathological bifurcation involvement (inter-radicular radiolucency), pathological internal and external root resorption. The final outcome was determined based on the recorded clinical and radiographic outcomes of each treatment performed at the last follow-up visit which included any clinical decisions that were taken in case of failed treatment such as tooth extraction because of pain or sepsis. The clinical and the final outcome were further described as successful, minor failure or major failure.

However, the radiographic outcome was not categorised further as there were no clear criteria in the literature to classify the unsuccessful radiographic finding. The criteria for scoring outcomes are summarised in Table 1.

Minor failure was defined as a failure that occurred within the treatment approach where the tooth remained restorable and didn't result in the tooth being extracted. While major failure was defined as a sequence of events that resulted in removal of the tooth as the final outcome such as the development of pain, sepsis or both.

Radiographic assessment

Pre and post-operative radiographs of each treatment were assessed by one trained and calibrated examiner (A.B.). The intra-examiner reliability Kappa score of the examiner was found to equal 0.90. The viewing conditions for each treatment approach were standardised.

A standard illuminated radiograph viewer, screened off, in a darkened room was used to analyse radiographs at LDI whereas radiographs at SCD were all digital (Sirona Heliodent DS intraoral X-ray generator, Bensheim, Germany).

Data recorded from radiographs included the initial diagnoses of the tooth (one surface cavity versus two surface cavities), extent of CL (CL in to enamel, dentine or pulp) as well as the pre- and post-operative radiographic diagnosis of the tooth and outcome of each treatment.

Data analysis

Data was entered into SPSS (Statistical Package for the Social Sciences) version 22. Data analysis was carried out at the tooth level and probability values of $p<0.05$ were considered statistically significant. To account for the clustering in the data, multi-level models were

used to analyse the data in the study. STATA version 12 (StataCorp) was used for this statistical modelling.

A mixed-effect logistic regression model using Stata 12 was fitted to test the association of the independent variables; treatment approach, treatment received, analgesia used, age of the patient at time of dental treatment, gender, and initial diagnosis of the tooth, with the variable of "remained asymptomatic". .

Survival rate of different treatment groups in the study was demonstrated using Kaplan–Meier survival analysis. Survival analysis was performed based on the final outcome "Survived"; teeth that remained asymptomatic in place till the last follow-up visit without exhibiting a minor or major failure. Moreover, a cox-proportional hazard model using Stata 12 was fitted with the "survived" as dependent variable. The independent variables included treatment approach, treatment received, age of the patient, gender, and initial diagnosis of the tooth. Teeth clustering were taken into account during all data analysis.

Results

Baseline characteristics (patients and teeth)

The clinical records of 1,200 patients were reviewed from LDI and SCD with 246 case notes fulfilling the inclusion criteria; 114 for the conventional approach and 132 for the biological approach. In total, the outcomes of 836 carious primary teeth were analysed; 428 and 408 teeth were from the conventional and biological approaches, respectively, achieving the sample size required (Figure 1).

Description of the study sample is outlined in Table 2. Children ranged in age from 4 to 9 years (median= 5.85 ± 1.52 years) with slightly more than half of the patients being female.

Significant differences were found among the two treatment approaches for the age of the patients, dmft and initial diagnosis of the CLs. The biological approach was carried out on a younger age group of children with lower dmft score compared to the conventional approach (p= 0.001). Children in the biological approach had a median age of 4 years (±1.5) and a median dmft of 7 compared to a median age of 6 years (±1.5) and dmft of 8 for the conventional approach (Figure 2). However, teeth in conventional approach had more multiple surface cavities than one surface cavity lesions (p= 0.03), than those in the biological approach.

Treatment characteristics

The details for the treatment received and restorations placed are shown in Table 3. Conventional and biological approaches were carried out on 51.2% and 48.8% of the teeth in the sample, respectively. Of the 836 teeth; 46.4% (388) had the Hall Technique, 38.8% (324) had complete CT removal, 12.4% (104) had pulpotomy and only 2.4% (20) received IPC. Resin composite was the restoration of choice for most of the teeth with complete CT removal (71.6%) while PMC were placed for most of the teeth with IPC (75%). All teeth that received a pulpotomy had been restored with a PMC.

Final Outcome of the two treatment approaches

Of the 836 teeth followed up for the study, 95.3% of the teeth in the conventional approach and 95.8% of the teeth in the biological approach remained asymptomatic in place at the final follow-up visit after a median follow-up of 13 (range 1-77 mo) and 9 months (range 1-63

mo), respectively. The data for all the four treatment methods in the two approaches, the major and minor failures and their reasons are presented in Table 4.

In addition, none of the independent variables including treatment approach, treatment received, analgesia used, age of the patient at time of dental treatment, gender, and initial diagnosis of the tooth were found to be a strong determinant of maintaining the tooth symptomless in place using mixed-effect logistic regression model.

Minor failure

There were only 6 minor failures recorded in the conventional approach. The reason reported for failure was the development of new CL at the margins of the restorations. The final outcome for these teeth was treatment of the new CL by complete CT removal and restoration of the cavity with PMC after a median time period of 19 months (range 7- 36). No minor failures were seen within the biological approach.

Major failure

Only 29 teeth (3.5%) experienced at least one major failure. As can be seen from Table 4 the distribution of failures was almost equal for both treatment approaches.

No significant difference was found between the two treatment approaches in term of teeth that remained symptom free until the final follow-up period of the study. There were also no significant differences in the outcomes between the two approaches when comparisons were made for the first or second primary molars.

Survival rate among the treatment types

In total, only 35 primary teeth out of 836 in the study were categorised as failure of treatment: 13 in complete CT removal group, 7 in pulpotomy, and 15 in Hall Technique.

As shown in Figure 3 Kaplan–Meier survival rate showed no statistically significant difference in the survival rates among the four treatment types in the current study (IPC, Hall Technique, complete CT removal and pulpotomy) ($P > 0.05$).

A cox proportional hazards model was applied to study any significant differences between the survival rate of the treatment received and the following variables: treatment approach, treatment received, age of the patient, gender, and initial diagnosis of the tooth regardless of the length of follow-up. No statistically significant differences were found between survival rates and the variables assessed (Table 5).

Discussion

The current study is one of the first to provide a direct comparison of the outcome of the two treatment approaches, conventional and biological in the treatment of deep CL in children in specialist settings. One of the strengths of this study is that the outcome of the biological restorative approach was compared to standard conventional restorative approach as currently practiced by specialists.

This study`s principal findings were that both approaches were highly successful (over 95%), the number of teeth that remained asymptomatic without exhibiting minor or major failures at the last follow-up visit did not differ significantly among the two treatment approaches. In addition, the success rates were not associated with age of patients, gender, lesion type, tooth and analgesia type. This finding could be explained by the fact that all

treatment included in the study were performed by specialist paediatric dentists where dental treatment was provided to patients at its highest standard using standardised techniques.

This is reflected by the small number of teeth that required further dental intervention after the provision of the initial treatment. Of 836 teeth included in this investigation, only 35 teeth presented with failed treatment and required further intervention: 20 teeth were from the conventional and 15 teeth were from the biological approach.

The findings of the present study do not concur with the findings of Innes[9,14] where it was reported that Hall Technique outperformed the conventional restoration. The main reason for this is probably the fact that the previous studies were carried out in primary care setting where the Hall Technique was compared to the restorations that the multiple general dentist practitioners had placed with variable techniques using a restorative materials with known high failure rate, such as conventional glass ionomer cements specially for proximal restorations in primary teeth. Indeed in these reported studies nearly three quarters (73%) of the restorations placed were conventional glass ionomer with 68% of the CL being proximal and 42% had advanced CL into dentine. Restoration of multiple surface CL in primary teeth has been shown to have a poorer outcome compared with other restorative materials[16]. However, the conventional approach in the present study involved the use of local analgesia, rubber dam whenever indicated, correct diagnosis of the pulp inflammation and provision of pulp therapy where required, thereby delivering a high level of successful outcome for teeth treated. However, we do acknowledge that the length of follow-up in our study had a wide range and a longer follow-up period could increase the reporting of these failures.

When analysing the reasons for small number of major failure in the two approaches, in the complete CT removal and pulpotomy groups, pain, sepsis or pain and sepsis was the commonest reason (3%), with the final outcome for these teeth being extraction. Among the biological approach, the Hall Technique exhibited very few major failures. Clinical pain, sepsis or both were seen among 15 teeth with Hall PMCs (4%) and these teeth were extracted as a final outcome. Of the 15, 11 teeth showed pathological intra-radicular radiolucency on radiographs.

Compared to the findings of the present study, a lower abscess rate (1.5%) was reported for the Hall Technique in two RCT's[9,14]. In another retrospective study by the same author[5,] however, a higher rate of tooth extraction (11%) was reported among the teeth which had been restored with the Hall technique, although this study reported on teeth that had been followed up after treatment for much longer period of time.

Significant differences in the baseline characteristics of the sample exist among the two treatment approaches for the age of the patients, dmft and initial diagnosis of the CL. This could have an impact on the outcome of the treatment, for example, more failures tend to occur among teeth with two or more surface lesions[9,17]. However, in the present study no statistical significant difference was seen among the two treatment approaches, the conventional and biological in terms of the number of failures using a mixed-effect logistic regression model after adjusting for the significant differences in baseline characteristics of the sample among the conventional and biological treatment approaches ($p > 0.05$ for age, gender, and dmft).

In the present study the Hall Technique and IPC were successful restorations in their own right, achieving comparable survival rates to standard conventional restorations placed under favourable conditions in teeth with more than half of the lesions having two or more surfaces,

a stage at which it is very likely there would be some pulpal involvement[18,19]. This is an interesting finding, as the Hall Technique involves no CT removal or tooth preparation unlike IPC which includes removal of some CT including the superficial plaque biofilm. The present study is one of several clinical studies supporting the approach of sealing dentinal dental caries within the tooth[2,3,6,11,12,13,20]

On the other side of the debate, there is also considerable evidence in the literature to support the philosophy that primary teeth restored following the principles of standard conventional restorative practice have excellent outcomes[17,21]. Although the conventional approach remains the most accepted restorative practice for the restoration of CL reaching the dentine in primary teeth worldwide, the data presented in the present study clearly shows that the biological approach can be practiced with excellent outcomes.

One advantage of the biological approach, the Hall Technique in particular, is that it does not require the use of local analgesia. Many general dental practitioners do not feel comfortable using local analgesia routinely for children and many children are understandably anxious about having injections. The use of a biological approach is clearly an excellent way of accomplishing high quality treatment for children with CL in primary and secondary care. However, the dental professional providing either type of care needs good behavioural management skills and training in the approach.

In the current study it was seen that the biological approach had been carried out on younger age group of children compared to the conventional restoration ($p= 0.001$). This could be related to the advantages biological restoration have over the conventional restorative approach in the treatment of CL in primary teeth for younger children. In the Hall Technique no local anaesthesia or any kind of tooth preparation is needed to fit the PMC while in IPC, the outer layer of CT is removed leaving the inner layer sealed in place mainly without LA.

Whereas in the conventional approach LA and rubber dam are needed most of the time which could be stressful for children aged 4 years old. It is likely that a large percentage of these younger children, treated successfully with a biological approach might have required pharmacological behaviour management for conventional restorative approach, such as the use of sedation or general anaesthesia (GA). The use of a biological approach could reduce the number of very young children who need general anaesthesia for comprehensive dental treatment because of their inability to cope with local analgesia. In turn, the potential benefits of this for health economic savings and also on morbidity of GA for a young child must be emphasised.

The present study demonstrates that when applied by operators at the specialist level of skill both conventional and biological treatment modalities, are equally effective in the management of deep dentinal caries in children.

Why this paper is important for paediatric dentistry

- This study contributes to the current debate on the treatment approaches for carious primary teeth in children. The results of this study show that conventional and biological treatment approaches had similar outcomes and were equally effective in the management of deep dentinal caries in children when used by paediatric dentists.
- Given the results of this study those paediatric dentists who do not use the biological approach should gain so can apply it when appropriate.
- With training in the biological approach clinicians could be able to accomplish treatment for many children with caries in primary care.

The authors have no conflict of interest to declare

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Figure Legends

Figure 1: Patient record search protocol and inclusion of the clinical records in the study.

Figure 2: Description of the age (years) of the patients at time of dental treatment in each treatment method for the conventional and biological approaches.

Figure 3: Kaplan-Meier survival curve for time to survival based on the final outcome of teeth that remained asymptomatic by treatment groups in the two treatment approaches.

Table 1: Description of the outcome criteria used to assess the success and failure of the two treatment approaches, conventional and biological, in the study.

Outcomes	Outcome Criteria
Clinical outcome	
Successful	▪ Remained Symptomless in place throughout the follow-up period (absence of pain related to the CL, tenderness to percussion, and clinical sepsis reported by patients and clinician) ▪ Restoration appeared satisfactory
Minor failures	▪ Premature exfoliation ▪ Clinical evidence of new carious lesion at the margins of a restoration ▪ Restoration lost and tooth remained asymptomatic (including PMC lost) ▪ Occlusal wear of restoration placed including PMCs
Major failures	▪ Development of pain ▪ Development of sepsis ▪ Development of pain and sepsis
Radiographic outcome	▪ Absence of pulp pathology ▪ PMC not seated properly ▪ Radiographic evidence of occurrence of new carious lesion at the margins of a restoration ▪ Pathological external/internal root resorption ▪ Pathological bifurcation involvement ▪ Post-operative radiographs not available
Final outcome	
Successful	▪ Remained asymptomatic in place ▪ Remained symptomless but extracted under GA with other painful teeth ▪ Natural exfoliation
Minor failures	▪ Restoration of new carious lesion at the margins of a restoration
Major failures	▪ Extracted because of pain, sepsis or both ▪ Given rise to the prescription of a course of antibiotic

Table 2: Baseline characteristics of the participants in the study sample including age (years), gender, teeth treated, initial diagnosis of teeth and dmft (sample size n = 246 patients and 836 teeth, conventional approach n = 114 patients and 428 teeth, biological approach n = 132 patients and 408 teeth).

Variable	Conventional approach n (%)	Biological approach n (%)	Study sample n (%)
Age at time of dental treatment			
Minimum	4.0 (14.9%)	4.0 (24.2%)	4.0 (19.9%)
Maximum	9.0 (7%)	9.0 (6.1%)	9.0 (6.5%)
Median	6.0 ± 1.52	4.0 ± 1.5	5.8 ± 1.52
Total	114 patients	132 patients	246 patients
Gender			
Male	51 (44.7%)	63 (47.7%)	114 (46.3%)
Female	63 (55.3%)	69 (52.3%)	132 (53.7%)
Teeth treated			
Second primary molar	224 (52.3%)	250 (61.3%)	474 (56.7%)
First primary molar	148 (34.6%)	157 (38.5%)	305 (36.5%)
Anterior	56 (13.1%)	1.0 (0.2%)	57 (6.8%)
Total	428 teeth	408 teeth	836 teeth
Initial diagnosis of teeth			
One surface cavity	180 (42.1%)	201 (49.3%)	381 (45.6%)
Two or more surface cavity	248 (57.9%)	207 (50.7%)	455 (54.4%)
Total	428	408	836
dmft			
Range	13	13	13
Median	8.0 ± 2.7	7.0 ± 2.6	7.0 ± 2.7

Table 3: Description of treatment received in the study including teeth treated, restorations placed, analgesia used, liner/base placed and isolation applied in each treatment method for the conventional and biological approaches.

Variable	Treatment received					
	Conventional approach			Biological approach		
	Complete CT removal (n=324)	Pulpotomy (n=104)	Total of conventional (n=428)	Hall Technique (n=388)	IPC (n=20)	Total of biological (n=408)
Teeth treated						
First primary molar	172 (53.1%)	52 (50%)	224 (52.3%)	241 (62%)	9.0 (45%)	250 (61.3%)
Second primary molar	97 (30%)	51 (49%)	148 (34.6%)	147 (38%)	10 (50%)	157 (38.5%)
Anterior	55 (17%)	1.0 (1%)	56 (13.1)	-	1.0 (5%)	1.0 (0.2%)
Restorations placed						
PMCs	89 (27.5%)	104 (100%)	193 (45%)	388 (100%)	15 (75%)	403 (98.7%)
Resin composite	232 (71.6%)	-	232 (54.2%)	-	1.0 (5%)	1.0 (0.2%)
Amalgam	3.0 (0.92%)	-	3.0 (0.7%)	-	-	-
Glass ionomer cement	-	-	-	-	4.0 (20%)	4 (0.9%)
Analgesia used						
Local anaesthetic (LA)	295 (91%)	91 (87.5%)	385 (90%)	-	11 (55%)	11 (2.7%)
Without LA	5.0 (1.5%)	-	5.0 (1.2%)	384 (99%)	9.0 (45%)	393 (96.3%)
Sedation with L.A	13 (4%)	11 (10.6%)	24 (5.6%)	-	-	-
General anaesthesia	11 (3.4%)	2.0 (1.9%)	14 (3.3%)	4.0 (1%)	-	4.0 (1%)
Liner/base placed						
Vitrebond	24 (7.4%)	-	24 (5.6%)	12 (3%)	7.0 (35%)	19 (4.7%)
Calcium hydroxide	3.0 (0.9%)	-	3.0 (0.7%)	-	1.0 (5%)	1.0 (0.2%)
G.I.C	4.0 (1.2%)	-	4.0 (0.9%)	-	-	-
None	293 (90.5%)	104 (100)	397 (92.8%)	376 (97%)	12 (60%)	388 (95.1%)
Isolation applied						
Rubber dam	322 (99.4%)	104(100%)	426 (99.5%)	-	-	-
None	2.0 (0.6%)	-	2.0 (0.5%)	388 (100%)	20 (100%)	408 (100%)

Table 4: Description of the final outcome of each treatment received in the study for the conventional and biological approaches and the reasons for minor and major failures in each group.

Final Outcome	Treatment received			
	Conventional approach		Biological approach	
	Complete CT removal (n=324)	Pulpotomy (n=104)	Hall Technique (n=388)	IPC (n=20)
Successful				
Remained asymptomatic	285 (88%)	90 (86.5%)	362 (93.3%)	18 (90%)
Remained asymptomatic but extracted under G.A	6.0 (1.8%)	3.0 (2.9%)	3.0 (0.8%)	-
Natural exfoliation	20 (6.3%)	4.0 (3.8%)	8.0 (2%)	2.0 (10%)
Minor failure				
Restoration of new carious lesion at the margins of restoration	6.0 (1.8%)	-	-	-
Major failure				
Extraction due to pain	-	1.0 (1%)	5.0 (1.3%)	-
Extraction due sepsis	7.0 (2.1%)	5.0 (4.8%)	10 (2.6%)	-
Prompted antibiotic	-	1.0 (1%)	-	-

Table 5: Correlations between the dependent variable of survived with other independent variables in the study (age, gender, initial diagnosis of tooth, treatment received, and treatment approach) using Cox-proportional hazards model

Outcome "Survived"	Hazard Ratio	Std. error	Z	P>(Z)	95% Confidence interval
Age	1.04	0.11	0.37	0.71	0.83-1.30
Gender					
Male (ref)					
Female	1.83	0.63	-1.75	0.08	0.83-3.61
Initial diagnosis of tooth					
One surface cavity (ref)					
Two or more surface cavities	0.65	0.22	-1.24	0.21	0.33-1.27
Treatment received					
Complete CT removal (ref)					
Pulpotomy	1.91	0.91	1.37	0.17	0.75-4.88
Hall Technique	1.02	0.39	0.07	0.94	0.48-2.19
IPC	0.85	0.67	-0.19	0.84	0.18-3.98
Treatment approach					
Conventional (ref)					
Biological	0.65	0.22	11.24	0.21	0.33-1.27

Figure-1: Patient record search protocol and inclusion of the clinical records in the study

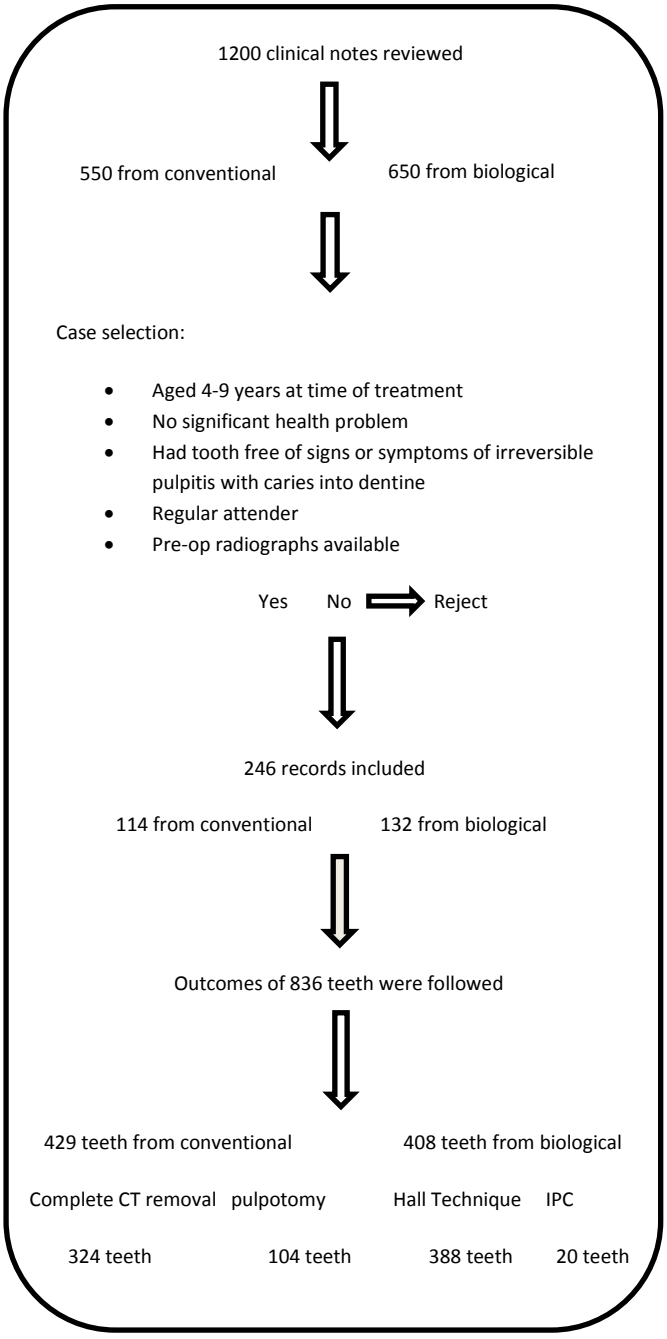

Figure 2: Description of the age (years) of the patients at time of dental treatment in each treatment method for the conventional and biological approaches.

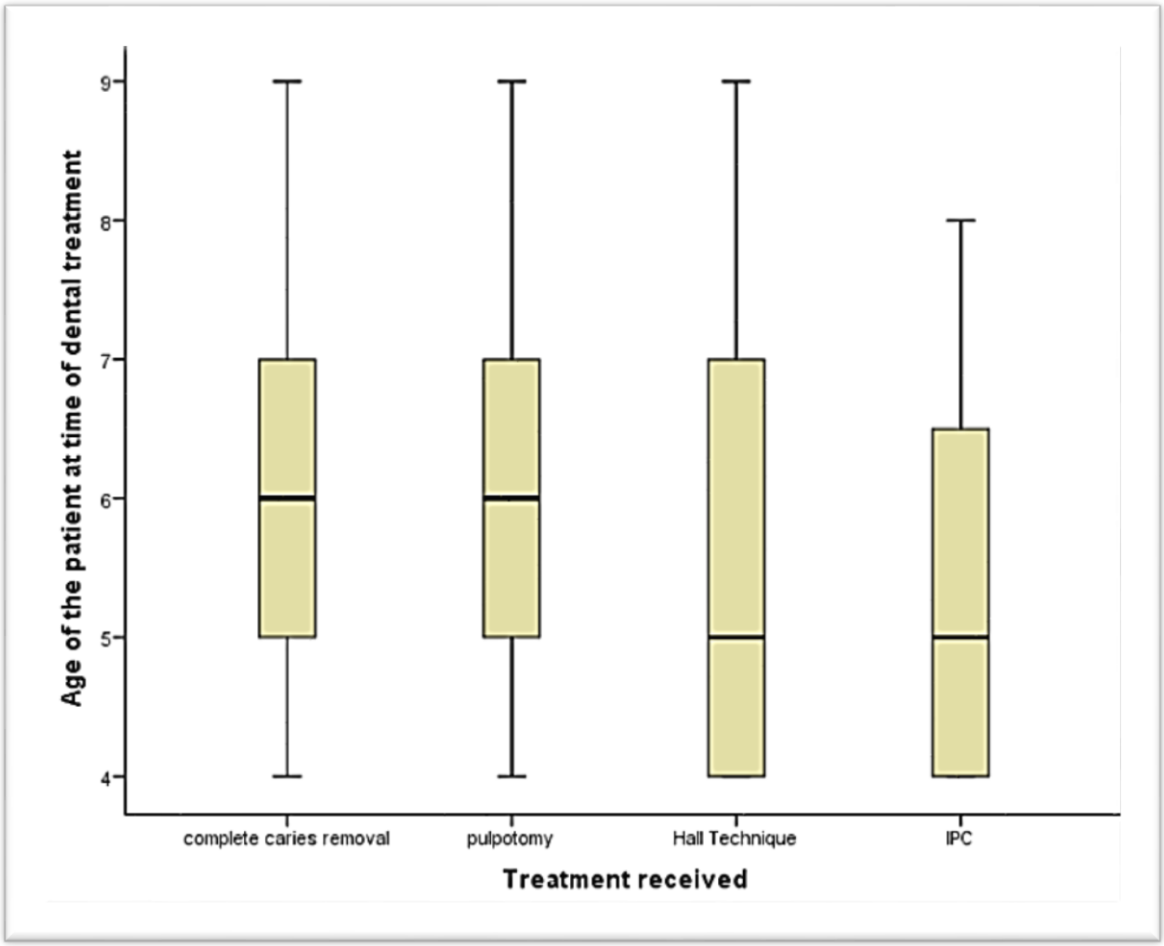

Figure 3: Kaplan-Meier survival curve for time to survival based on the final outcome of teeth that remained asymptomatic by treatment groups in the two treatment approaches